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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,724	01/03/2001	Masafumi Kitakaze	58777.000003	1212

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EXAMINER

MITRA, RITA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/10/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/752,724

Applicant(s)

KITAKAZE, MASAFUMI

Examiner

Rita Mitra

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Application/Control Number: 09/752,724

Page 2

Art Unit: 1653

DETAILED ACTION***Status of the Claims***

Applicants' preliminary amendments filed on April 24, 2001 and May 14, 2001 in paper #6 and 9 respectively are acknowledged. Claim 1 has been amended. Claims 1-10 are currently pending and are under examination.

Informalities

The disclosure is objected to because of the following informalities:

On page 1 line 1 the priority/continuing data is missing.

The amended claim 1 in paper #9 is objected to because it repeats the line 2 at page 1 in line 1 at page 2. Appropriate correction is required.

Priority

Applicant's claim for foreign priority under 35 U.S.C. 119 (a-d) is acknowledged. This application claims a priority of a Japanese Application No. 98134/2000, filed on March 31, 2000. Although, the instant application has provided a copy of this application, it fails to provide a certified copy of English translation in support of the priority date claimed. Therefore, the priority date granted is January 3, 2001, which is a filing date of this application.

Information Disclosure Statement

The information disclosure statement filed April 24, 2001 is acknowledged. The reference D, which is listed in the PTO-1449 form, is a Japanese publication and a copy of an English translation of this reference was not submitted in the IDS. Therefore, PTO-1449 has been placed in the application file and considered with regard the references, which have been submitted except reference D because an English translation of the reference D has not been supplied with this application. Note that reference D has been lined through. Consideration of the lined through reference will be made upon compliance with 37CFR 1.98 (a) (2).

Objections to Claims

Claims 4, 5, 9 and 10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or, it cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claims 4, 5, 9 and 10 are multiply dependent from previous multiple dependent claims 3 and 8 respectively. Claims 4, 5, 9 and 10 have been reviewed on the basis that they depend solely from the first listed claim in the multiple dependencies. It is incumbent upon applicant to properly amend the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 5 are indefinite because they are multiple dependent from a previous multiple dependent claims 3 and 4 respectively.

Claims 9 and 10 are indefinite because they are multiple dependent from a previous multiple dependent claims 8 and 9 respectively.

Claims 1-10 are indefinite because of the use of the term "cGMP". An acronym/abbreviation should be preceded by the full spelled out word. Claims 2-5 and 7-10 are included in the rejection because they are dependent on rejected claim and do not correct the deficiency of the claim from which they depend.

Claims 6-10 are indefinite because they lack essential steps as claimed in the process of treatment or prophylaxis of ischemic heart diseases. The omitted steps are: the site and method of administration, the therapeutically effective amount of the agent and a step whereby the

Art Unit: 1653

desired outcome and the time for the effective treatment using natriuretic peptide can be determined. Claims 7-10 are included in the rejection because they are dependent on rejected claim and do not correct the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Takata et al. (Cardiovascular Research, 32, 286-293, 1996). Takata et al. teach a pharmaceutical composition that comprises an effective amount of synthetic alpha human ANP (atrial natriuretic peptide) (claim 1, 4 and 5), which increases the level of cyclic guanosine monophosphate (cGMP) (claim 1), and has cardioprotective effects (claims 1) on myocardial ischemia (claim 3) and reperfusion injury (claim 2) (see abstract; page 287, col 1, lines 12-14 and 24-25; page 289, col 1, lines 35-39; Fig. 1 and Table 1). Therefore, Takata's composition meets the criteria of claims 1-5 of instant application.

Takata et al. also teach a method of cardioprotection (claim 6) of myocardial ischemia (claims 8) and reperfusion injury (7) by administering a composition comprising an effective amount of synthetic alpha human ANP (atrial natriuretic peptide) (claim 6, 9 and 10), which increases the level of cyclic guanosine monophosphate (cGMP) (claim 6), and has cardioprotective effects on myocardial ischemia and reperfusion injury (claims 6, 7, 8), (see abstract; page 287, col 1, lines 12-14 and 24-25, col 2, lines 14-18; page 289, col 1, lines 35-39; Fig. 1 and Table 1). Therefore, Takata's method anticipates claims 6-10 of instant application.

Art Unit: 1653

Conclusions

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.

September 7, 2002



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